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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/403,803	03/17/1995	RON S. ISRAELI	41426-A-PCT-	4181

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EXAMINER	
GUCKER, STEPHEN	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/403,803	ISRAELI ET AL.	
	Examiner	Art Unit	
	Stephen Gucker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *28 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *127-129* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *127-129* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/1/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.

3. Claims 127-129 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of US 5,538,866 in view of Lerner. The patented claims teach isolated nucleic acids, vectors, plasmids, host cells, and methods for producing prostate specific membrane antigen (PSMA). The patented claims do not teach 15-mer or longer nucleic acid fragments of PSMA (instant SEQ ID NO:1 being the naturally occurring nucleic acid (e.g. "gene") sequence encoding PSMA, instant SEQ ID NO:2 being the amino acid sequence of PSMA). Lerner teaches the usefulness of using smaller regions of nucleic acids or genes to produce antibodies specific for select regions of the encoded protein's structure (pages 11, 14-17, and 23), and then the antibodies can be used as highly selective and specific probes for the encoded protein in question. It would have been obvious at the time of the invention for one of ordinary skill in the art to make and use the small PSMA nucleic acid fragments of the present invention from the larger patented nucleic acids in order to make highly specific antibody probes for any particular region of the PSMA as taught by Lerner. As Lerner teaches, the practitioners of the antibody arts would be highly motivated to use small nucleic acids to make small peptides for certain small regions of the PSMA protein in order to make antibodies selective and specific for those regions so

that the structure and functioning of the PSMA could be studied and distinguished from any PSMA alternate splice variants, soluble fragments, mutations, etc. as discussed for many proteins in general by Lerner, rendering the instant claims *prima facie* obvious.

Applicant's arguments filed 11/28/05 have been fully considered but they are not persuasive because Applicant argues that instant claims 127 and 129 which are limited to SEQ ID NO:1 and fragments thereof, cannot be an obvious species from the genus of encoding nucleic acids recited in claim 1 of the '866 patent (an encoding nucleic acid sequence for SEQ ID NO:2). However, the rejection includes not just claim 1 of the '866 patent, but also claim 9. Claim 9 of the '866 patent is a deposited plasmid which comprises SEQ ID NO:1 which is the same for both the patent and the instant application. The '866 patent clearly states at column 10, lines 24-32, that in an embodiment, the PSMA sequence is cloned into a plasmid and deposited with the ATCC with Accession Number 75294 (same as claim 9 of the '866 patent). This plasmid comprises the endogenous, naturally occurring sequence or gene (see column 21, lines 25-27 of the '866 patent, which states that SEQ ID NO:1 is the gene that encodes the 100 kD PSM antigen), found in the human body, that encodes SEQ ID NO:2, and this naturally occurring sequence comprises SEQ ID NO:1. So, in contrast to Applicant's assertions that there are no teachings in patented claim 1 that exemplify one encoding species over another, in line with Applicant's citation of In re Deuel, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995), the Examiner does not find Applicant's arguments convincing because patented claims 1 and 9 teach the naturally occurring SEQ ID NO:1 as an exemplified species of the genus claimed in patented claim 1. Using an

endogenous gene or fragments thereof, that occur naturally, is prima facie obvious over using any other degenerate sequences due to the facts that the endogenous sequence requires no extra work in translating the genetic code over a synthetic, man-made sequence, and the endogenous sequence would be the sequence that would be most preferred for skilled artisans for making probes out of in order to search for other closely related sequences, such as alternative splice variants or from different animal species, through the processes of nucleic acid hybridization, as synthetic, man-made artificial sequences would contain more mismatches between the bases of the hybridizing nucleic acids than the endogenous, natural gene sequence would possess, thus making SEQ ID NO:1 or fragments thereof, better nucleic acid probes, which could also be used to make peptide fragments in order to produce selectively binding antibodies.

In regards to Applicant's other argument that Lerner does not teach SEQ ID NO:1 or fragments thereof, this argument is unpersuasive because Applicant is arguing the references in isolation and not in combination, as detailed above and in the original rejection, and the references in combination is the correct standard to apply.

4. Claims 127-129 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of US 5,935,818 in view of Lerner. The patented claims teach isolated nucleic acids, vectors, host cells, and methods for producing alternately spliced prostate specific membrane antigen (PSMA'). The patented claims do not teach 15-mer or longer nucleic acid fragments of PSMA'. Lerner teaches the usefulness of using smaller regions of nucleic acids or genes to produce antibodies specific for select regions of the encoded protein's structure (pages

11, 14-17, and 23), and then the antibodies can be used as highly selective and specific probes for the encoded protein in question. It would have been obvious at the time of the invention for one of ordinary skill in the art to make and use the small PSMA' nucleic acid fragments of the present invention from the larger patented nucleic acids in order to make highly specific antibody probes for particular regions of the PSMA' as taught by Lerner. As Lerner teaches, the practitioners of the antibody arts would be highly motivated to use small nucleic acids to make small peptides for certain small regions of the PSMA' protein in order to make antibodies selective and specific for those regions so that the structure and functioning of the PSMA' could be studied and distinguished from any PSMA' alternate splice variants, soluble fragments, mutations, etc. as discussed for many proteins in general by Lerner, rendering the instant claims *prima facie* obvious.

Applicant's arguments filed 11/28/05 have been fully considered but they are not persuasive because Applicant argues that instant claims 127 and 129 which are limited to SEQ ID NO:1 and fragments thereof, cannot be an obvious species from the genus of encoding nucleic acids recited in claim 1 of the '818 patent (an encoding nucleic acid sequence for SEQ ID NO:2). However, the rejection includes not just claim 1 of the '818 patent, but also claim 10. Claim 10 of the '818 patent is a naturally occurring sequence from humans (SEQ ID NO:39) which is part of the naturally occurring sequence of instant SEQ ID NO:1, which is the same in both the patent and the instant application. So, in contrast to Applicant's assertions that there are no teachings in patented claim 1 that exemplify one encoding species over another, in line with Applicant's citation of In

re Deuel, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995), the Examiner does not find Applicant's arguments convincing because patented claims 1 and 10 teach, at least, part of the naturally occurring SEQ ID NO:1 as an exemplified species of the genus claimed in patented claim 1. Using an endogenous gene or fragments thereof, that occur naturally, is prima facie obvious over using any other degenerate sequences due to the facts that the endogenous sequence requires no extra work in translating the genetic code over a synthetic, man-made sequence, and the endogenous sequence would be the sequence that would be most preferred for skilled artisans for making probes out of in order to search for other closely related sequences, such as alternative splice variants or from different animal species, through the processes of nucleic acid hybridization, as synthetic, man-made artificial sequences would contain more mismatches between the bases of the hybridizing nucleic acids than the endogenous, natural gene sequence would possess, thus making SEQ ID NO:1 or fragments thereof, better nucleic acid probes, which could also be used to make peptide fragments in order to produce selectively binding antibodies.

In regards to Applicant's other argument that Lerner does not teach SEQ ID NO:1 or fragments thereof, this argument is unpersuasive because Applicant is arguing the references in isolation and not in combination, as detailed above and in the original rejection, and the references in combination is the correct standard to apply. Applicant's additional argument that the '818 patent excludes the underlying encoding sequence of 13 amino acids is unconvincing as the vast majority of the instant invention is obvious

over the references, not that the combined references encompass completely the instant invention, as is the case above with the other double patenting rejection.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 128-129 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of the claims are indefinite because while the claims recite "at least 15 consecutive nucleotides," the claim also recites "has a sequence which is the same as a sequence of all of an outside region of prostate specific membrane antigen," which, by the Examiner's calculations, must be at least 2118 consecutive nucleotides in length (750 amino acids minus 44 amino acids equals 706 amino acids, multiply by three, equals 2118 nucleotides). Do the claims intend to encompass at least 15 consecutive nucleotides or at least 2118 consecutive nucleotides?

6. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

7. No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached at (571) 272-0867. The fax phone number for this Group is currently (571) 273-8300.

SG

Stephen Gucker

February 5, 2006

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER